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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,389	12/10/2001	Jean-Noel Thorel	108961.01	8418

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EXAMINER

HOFFMAN, SUSAN COE

ART UNIT	PAPER NUMBER
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1655

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/006,389	Applicant(s) THOREL, JEAN-NOEL	
	Examiner Susan Coe Hoffman	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,7,10-13,16,18-21 and 29 is/are pending in the application.
- 4a) Of the above claim(s) 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,7,10-13,16,18-21 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The amendment filed April 22, 2009 has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claims 2, 4-6, 8, 9, 14, 15, 17, 22-28 and 30-35 have been cancelled.
3. Claims 1, 3, 7, 10-13, 16, 18-21 and 29 are pending.
4. In the reply filed on April 29, 2008, applicant elected water and triglycerides for the species with traverse.
5. Claim 21 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.
6. Claims 1, 3, 7, 10-13, 16, 18-21 and 29 are examined on the merits.

Claim Objections

7. Claim 13 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 13 is broader in scope in comparison to claim 1. Claim 1 states that the composition consists of biodermal constituents while claim 13 states that the composition comprises water (a biodermal constituent). "Comprising" is open claim language while "consisting of" is closed claim language. Thus, the use of "comprising" in claim 13 does not further limit claim 1 because claim 13 allows for the inclusion of additional elements in the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 13 is indefinite because it conflicts in scope with claim 1. Claim 1 states that the composition consists of biodermal constituents while claim 13 states that the composition comprises water (a biodermal constituent). "Comprising" is open claim language while "consisting of" is closed claim language. Thus, the use of "comprising" in claim 13 is confusing because it conflicts with the closed language used in claim 1.

Claim Rejections - 35 USC § 103

9. Claims 1, 3, 7, 10-13, 16, 18-21 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein (US 5,508,034) in view of Wilder (US 4,695,456) and La Tour (US 4,634,436).

Bernstein teaches a composition for treating the skin. The composition comprises three classes of lipids naturally found in the stratum corneum layer of the skin including triglycerides, cholesterol and lecithin (see column 1, line 49 - column 2, line 18 and claims). The reference also teaches that water can be used as a vehicle (see Examples). The composition can be applied with only the skin lipids, non-biodermal ingredients are not specifically required (see abstract

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and column 1, lines 53-54). The reference does not specifically teach formulating the composition into a two phase form that consists only of biodermal constituents.

Wilder teaches that skin irritation is caused by chemical irritants found in cosmetics (see column 1, lines 7-10). Wilder teaches that to avoid skin irritation, cosmetics should be formulated into creams, emulsions, oil-in-water or water-in-oil emulsions, and other known cosmetic forms using non-allergenic carriers. The reference specifically suggests using 50 to 100% water as such a non-allergenic carrier (see column 5, lines 9-13 and 33-35, claims 1, 6 and 8). La Tour teaches that lecithin is an emulsifier (see column 2, lines 24-29). Thus, an artisan would expect that adding water to the lecithin and triglycerides taught by Bernstein would form a non-allergenic emulsion such as those taught by Wilder. An artisan would be motivated to make such a composition because the artisan would reasonably expect that using only non-allergenic, skin components would produce a non-irritating cosmetic.

The references also do not specifically teach adding the triglycerides in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Bernstein teaches using a range of between 25 to 75% fatty acids in the forms of triglycerides in the lipid concentrate. In addition, the reference teaches using between 1 to 50% of the lipid concentrate (see column 2, lines 15-20). Thus, by teaching a range of triglyceride amounts, Bernstein acknowledges that the amount of triglyceride in the composition is a general condition that can be optimized by routine experimentation. Therefore,

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an artisan would have been motivated to modify the amount of triglyceride in the combination suggested by the combined reference in order to formulate a product that best achieves the desired results set forth in the references. Thus, absent some demonstration of unexpected results from the claimed parameter, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

10. Claims 1, 3, 7, 10-13, 16, 18-20, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seidel (WO 95/22313 - US 5,830,483 is the English translation of WO '313, for ease it will be referred to in the rejection) in view of Bernstein (US 5,508,034), Wilder (US 4,695,456) and La Tour (4,634,436).

Seidel teaches a topical oil-in-water emulsion which contains 50 to 99% water, 1 to 30% of an oil phase and below 1% by weight of an emulsifier (see column 1, lines 31-44). The reference teaches that the oil phase can be made up of triglycerides (see claims 1 and 13). However, the reference does not specify the use of biodermal triglycerides or biodermal emulsifiers.

Bernstein teaches making cosmetic compositions using triglycerides extracted from the stratum corneum of the skin. The reference teaches that cosmetics made with these stratum corneum components are superior in comparison to cosmetics that are not made with these components (see column 1, lines 33-end). Thus, an artisan of ordinary skill would reasonably expect that stratum corneum triglycerides could successfully be used as the source of the triglycerides in the oil phase of the emulsion taught by Seidel. An artisan would expect this modification to improve the composition of Seidel as suggested by Bernstein. This reasonable

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expectation of success would have motivated the artisan to modify Seidel to include biodermal triglycerides in the emulsion.

Bernstein also teaches that lecithin is a component present in the skin. Wilder teaches that skin irritation is caused by chemical irritants found in cosmetics (see column 1, lines 7-10). Wilder teaches that to avoid skin irritation, cosmetics should be formulated into creams, emulsions, oil-in-water or water-in-oil emulsions, and other known cosmetic forms using non-allergenic carriers. La Tour teaches that lecithin is an emulsifier (see column 2, lines 24-29). Thus, an artisan of ordinary skill would reasonably expect that the composition of Seidel could be improved if a non-allergenic emulsifier was used in the emulsion taught by Seidel. An artisan would expect that lecithin would be useful as such a non-allergenic emulsifier because it is a component that is naturally present in the skin. An artisan would expect that the skin would not exhibit sensitivity to its natural constituents. Therefore, this reasonable expectation of success would motivate the artisan to form two phase emulsions using water, triglycerides from the skin and lecithin from the skin.

The references also do not specifically teach adding the triglycerides in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Bernstein teaches using a range of between 25 to 75% fatty acids in the forms of triglycerides in the lipid concentrate. In addition, the reference teaches using between 1 to 50% of the lipid concentrate (see column 2, lines 15-20). Furthermore, Seidel

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teaches using between 1 to 30% of the oil phase. Thus, by teaching a range of triglyceride amounts, Bernstein and Seidel acknowledge that the amount of triglyceride in the composition is a general condition that can be optimized by routine experimentation. Therefore, an artisan would have been motivated to modify the amount of triglyceride in the combination suggested by the combined reference in order to formulate a product that best achieves the desired results set forth in the references. Thus, absent some demonstration of unexpected results from the claimed parameter, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

11. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Coe Hoffman/
Primary Examiner, Art Unit 1655